DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 20, 2015

Biomet 3i
Mr. Chris McKee
Regulatory Affairs Manager
4555 Riverside Drive
Palm Beach Gardens, Florida 33410

Re: K150571
Trade/Device Name: *3i* T3® Short Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: October 15, 2015
Received: October 16, 2015

Dear Mr. McKee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K150571

Device Name: ***3i*** T3® Short Implants

Indications for Use:

The ***3i*** T3® Short Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

Prescription Use __X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

3i T3® Short Dental Implants
510(k) Summary
November 20, 2015

I. Company: BIOMET *3i*™
4555 Riverside Drive
Palm Beach Gardens, Florida 33410
(561) 776-6923

Contact: Chris McKee
Regulatory Affairs/Regulatory Compliance Leader

II. Proprietary Trade Name: ***3i*** T3® Short Implants

III. Classification Name: Implant, Endosseous, Root-Form (21 CFR 872.3640)

IV. Classification: Class II

V. Product Code(s): DZE

VI. Reason for 510(k)
The purpose of this 510(k) was to expand BIOMET ***3i***'s dental implant product offering by adding dental implants with a multi-level surface topography like the existing ***3i*** T3® Ex Hex Dental Implants but with shorter lengths called the ***3i*** T3® Short Implants. In addition, MR compatibility information is being added to the device labeling for Biomet 3i dental implants (inclusive of the subject devices) and restorative devices.

VII. Product Description
The ***3i*** T3® Short Implants are manufactured from commercially pure titanium and feature a roughened apex and traditional OSSEOTITE® coronal surface. In addition, the implants are offered with or without a nano-scale discrete crystalline deposition (DCD®) calcium phosphate (CaP) surface treatment. The dental implants are basic screw-type designs available in parallel walled body geometries with an external hex connection for mating with associated Biomet ***3i***™ external connection restorative components. The implants are offered in 5.0mm and 6.0 mm diameters and 5.0mm and 6.0mm lengths to accommodate varying patient anatomy. Size appropriate cover screws are provided with each implant.

VIII. Indications
The ***3i*** T3® Short Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed loading, or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures.

IX. Summary of the Technological Characteristics
The subject devices provide additional implant options for connection to existing Biomet ***3i***™ external hex restorative components. The primary change from the predicate ***3i*** T3® devices in K133049 is the shorter length. The external connection is the same as the other predicate external connection dental implants. The materials, implant body designs, and surface treatments are identical as the listed primary predicate device. The size offerings are also the same as the secondary predicate device.

Unlike the primary predicate device, the subject devices are not indicated for immediate loading. The removal of this indication for the subject devices does not alter their intended use described within Section VIII above, as it is only related to the timing in which the implant can be placed into occlusal loading after implantation. The remaining indications for delayed loading are identical to the primary predicate device. Furthermore, the intended use and remaining indications are equivalent to the secondary predicate device which is similar in size. Based on these equivalencies along with those demonstrated through non-clinical testing, the removal of immediate loading from the indications of the subject devices does not raise any new questions of safety or effectiveness.

X. Identification of Legally Marketed Devices

The design features, materials, and indications for use of the subject devices are substantially equivalent to Biomet ***3i*** predicate device noted below:

- ***3i*** T3® External Hex Dental Implants (K133049 SE 1/8/2014)

The size of the subject devices are substantially equivalent or similar to the secondary predicate device noted below:

- Bicon Short Implant (5.0mm and 6.0mm, K073368 SE 10/10/2008, K062044 SE 11/21/2006 and K042637 SE 11/15/2004)

XI. Discussion of the Non-Clinical Testing

Non-clinical testing was performed on the worst case subject devices in the form of fatigue testing in accordance with ISO 14807:2007 and FDA guidance. The results were compared to the previously listed predicate devices in K133049. The subject devices met the pre-determined acceptance criteria.

Additional non-clinical testing was performed on the worst case subject devices and the worst case predicate Bicon devices in the form of implant surface area analysis, bone to implant contact analysis and pullout strength analysis. The results of the head-to-head testing were compared and it was determined that the subject devices were substantially equivalent to the predicate Bicon devices in all three tests.

Because the subject devices are manufactured out of identical materials and by identical processes, the primary predicate device biocompatibility data was leveraged.

MR compatibility testing was conducted on the worst case cleared Biomet 3i device constructs utilizing multiple material configurations. Testing included RF heating, MR artifacts, displacement force, and torque under static magnetic fields of 1.5 Tesla (1.5T) and 3.0 Tesla (3.0T) in accordance with FDA Guidance Document [Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance (MR) Environment], ASTM F2052-06e, ASTM F2213-06, ASTM F2119-07, and ASTM F2182-11a. The results of the testing demonstrated that the Biomet 3i dental implants (inclusive of the subject devices) and restorative devices are considered to be MR Conditional in both 1.5T and 3.0T MR environments. This has been reflected in the device labeling.

XII. Conclusions

The subject devices have demonstrated substantial equivalence to the previously listed predicate devices in that they utilize identical materials and fundamental designs, have the same intended use, and performed equivalently in the aforementioned non-clinical testing.